IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Ian D. Faulkner
Application No.	:	10/731,828
Filing Date	:	December 9, 2003
Art Unit	:	3735
Title	:	Sterile Radioactive Seeds
Docket No.	:	PZ9918

Mail Stop Appeal Brief – Patents
Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

APPEAL BRIEF

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I. REAL PARTY IN INTEREST

The real party in interest in this Appeal is Amersham plc (now GE Healthcare Limited, a part of General Electric "GE").

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences related to the instant appeal.

III. STATUS OF CLAIMS

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 are pending in this application. The Examiner has rejected all of these claims. These claims as amended during prosecution are reproduced in the **Claims Appendix** attached hereto. Appellants are appealing the rejections of Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19.

IV. STATUS OF AMENDMENTS

Appellants filed a Response on January 17, 2007 and a final Office Action was mailed on March 28, 2007. No claims were amended subsequent to the Examiner's final rejection that was mailed on March 28, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1 describes a method of sterilising one or more radioactive seeds, which method comprises subjecting the radioactive seeds to dry heat at a temperature of at least 140°C for a minimum of 2 hours to effect sterilisation, and subsequently cooling the radioactive seeds.

Support for claim 1 can be found on page 3, lines 8-20 and page 5, lines 24-26 of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues for review in this appeal arise from a Final Rejection that was mailed on March 28, 2007. The Examiner rejects claims 1, 3-5, 7-10, 12-13, 15 and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,460,592 ("Langton") in view of U.S. Patent No. 5,863,790 ("Bolea").

The Examiner also rejects claim 4 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,106,455 ("Kan") in view of the combination of Langton and Bolea as applied in claim 1.

Claims 3-5, 7-10, 12-13, 15 and 18-19 are dependent on claim 1 and inherit all the limitations set forth in claim 1. Therefore, the issues in this appeal are:

1. Whether Langton in view of Bolea disclose, teach, or suggest all the elements of claims 1, 3-5, 7-10, 12-13, 15 and 18-19?

VII. ARGUMENT

The Examiner rejects claims 1, 3-5, 7-10, 12-13, 15 and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,460,592 ("Langton") in view of U.S. Patent No. 5,863,790 ("Bolea").

Appellants respectfully request that The Board of Patent Appeals and Interferences ("Board") should reverse the Examiner's rejections for the reasons set forth below.

A. The Examiner's Rejections of Claims 1, 3-5, 7-10, 12-13, 15 and 18-19 Should be Reversed Since Langton in view of Bolea Fails to Teach All the Elements of the Claims

Before discussing the specific differences between the prior art and the present invention, Appellants respectfully submit that it is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986). (emphasis added).

On the bottom of page 4 of the final Office Action dated March 28, 2007 ("Office Action"), the Examiner states "Langton et al. does not indicate that one-hour of dry heat will stiffen and sterilize the seed strand only that the one-hour of dry heat limit will "stiffen" the seed strand." It is well settled in case law that prior patents such as Langton and Bolea are references only for what they clearly disclose or suggest. Additionally, it is not proper use of a patent as a reference to modify its structure to one which prior art references do not suggest. *In re Randol and Redford*, 425 F.2d 1268, 165 U.S.P.Q. 586, 588 (C.C.P.A. 1970). Hence, the Examiner can not make the assumption that Langton sterilizes the seed at least one hour longer after stiffening it when Langston does not even disclose or teach this let alone suggest it.

Furthermore, on page 5 of the Office Action, the Examiner states that "if the seed strand of Langton et al. were to be stiffened and sterilized separately the process would be as follows as set forth by Langton…..". First, Appellants point out, that unlike the present invention's utilization of temperature dependent dry heat sterilization, Langton vaguely discloses the use of a gas or gamma irridation to sterilize the tubular sheath.

Additionally, the Examiner agrees with Appellants that Langton does not set forth dry heat sterilization in a procedure where the strand is stiffened and sterilized. On page 5 of the Office Action, the Examiner further states that "it would have been obvious to use dry heat sterilization in place of gas or gamma radiation. Appellants respectfully disagree. First, Appellants point out that Langton does not disclose, teach, or suggest using dry heat for sterilization purposes. Moreover, as Appellants indicate in the specification of the present invention on pages 7-11, the choice of dry heat for sterilizing radioactive seeds is not an obvious or natural one. To illustrate this point, a discussion of the various sterilization methods can be found on pages 7-11 of the specification.

Additionally, unlike gamma irradiation and other process, the dry heat sterilization process of the present invention has the advantage that it is quick, uses equipment typically found in a production laboratory, is relatively easy to validate and control, and gives a very high sterility assurance level. Other advantages for using this process over gamma irradiation and other process is that the sealed seed container in the present invention does not need to be open during the process, hence it is a genuine terminal sterilization. There is also no

need for specific assays or checks to ensure removal of toxic chemicals, and the product is in a form which is convenient to use for the customer.

Dry heat sterilization to a seed or a tubular sheath is not one which would be apparent to one skilled in the art when viewing Langton. In using the dry heat sterilization process Langton would need to account for the strong heating of the sealed sheath that would contain a volatile radionuclide which would imply an attendant risk of internal pressure developing. Clearly any rupture of a sheath would cause a serious escape of radioactivity.

Accordingly, the claims of the present invention can not then be merely assumed obvious from the Examiner's subjective view point. Appellants note that "the prior art itself must provide a motivation or reason for the worker in the art, without the benefit of the Applicant's specification, to make necessary changes in the reference device". See, *Ex parte Chicago Rawhide Manufacturing Co.*, 226 U.S.P.Q. 438 (PTO Bd. App. 1984).

Furthermore, Appellants respectfully stress that it is well settled in the law that a reference must be considered not just for what it expressly teaches, but also for what it fairly suggests to one who is unaware of the claimed invention. *In re Baird*, 16 F.3d 380, (Fed. Cir. 1994).

Additionally, even assuming, *arguendo*, that Langton and Bolea are properly combinable; Appellants respectfully submit that any such combination would teach away from

the present invention. 'Teaching away' simply means teaching a solution that would not lead to the claimed subject matter. As noted by the Federal Circuit:

> A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. (emphasis added).
>
> *Para-Ordnance Mfg. v. SGS Importers Int'l*, 73 F.3d 1085 (Fed. Cir. 1995).

Appellants respectfully submit that Langton clearly only discloses the use of gas or gamma irradiation to sterilize the sheath or an autoclave system to heat/stiffen and sterilize the sheath. (see column 3, lines 5-13). Langton thereby teaches away from using a dry heat sterilization process. Again, this process would not be apparent to one skilled in the art when viewing Langton. If Langton used a dry heat sterilization process it would require strong heating of a sealed capsule containing a volatile radionuclide which would imply an attendant risk of internal pressure developing. Clearly any rupture of the sheath would cause a serious escape of radioactivity. Langton does not disclose, teach, or suggest any of these issues.

Furthermore, Langton does not even disclose, teach, or suggest using a dry heat sterilization process to stiffen and sterilize a strand. It is important to note that on page 7 of the Office Action, the Examiner states "Langton et al. does teach dry heat sterilization…..". Appellants respectfully request that the Examiner point out where Langton specifically teaches or even suggest the dry heat sterilization process that is used by the present invention.

Further, as agreed upon by the Examiner on page 7 of the Office Action, Bolea does not even teach dry heat sterilization of radioactive seeds. The Examiner further states that it is believed that Bolea teaches dry heat sterilization time periods even though Bolea does not teach dry heat sterilization at least like the present invention. Appellants are somewhat confused about the Examiner's leap of combinding Langton with Bolea here. It appears that the Examiner is subjectively apply his own personal views here.

Additionally, on page 7 of the Office Action, the Examiner states that Applicant has failed to show that Langton sterilizes and stiffens the seed strand in only one hour. Appellants made this statement because it is pure speculation as to how long Langton intended it would take to sterilize the sheath. Langton gives a vague outline of sterilization done by gas or gamma irradiation on column 2, line 56 to column 3, line 13 and mentions no time requirements. Moreover, Appellants have already demonstrated above that neither Langton or Bolea disclose, suggest, or teach all the elements of the present invention. Accordingly, Appellants believe this is a moot point now.

Appellants therefore respectfully request that the Board should reverse the Examiner's obviousness rejection of claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19.

Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,106, 455 in view of the combination of Langton and Bolea. This rejection is respectfully traversed. Claim 4 is dependent on claim 1 and inherits all the limitations set forth in

claim 14. Appellants therefore respectfully request that the Board should reverse the Examiner's obviousness rejection of claim 4.

CONCLUSION

In view of the foregoing, Appellants respectfully request that the Board reverse the rejections of Claims 1, 3-5, 7-10, 12-13, 15 and 18-19 as set forth in the Office Action mailed March 28, 2007, that the Board allow the pending claims since they are in condition for allowance, and that the Board grant any other relief as it deems proper.

Dated: September 24, 2007

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A method of sterilising one or more radioactive seeds, which method comprises subjecting the radioactive seeds to dry heat at a temperature of at least 140˚C for a minimum of 2 hours to effect sterilisation, and subsequently cooling the radioactive seeds.

2. (Canceled)

3. The method of claim 1, wherein the temperature is at least 160 ˚C.

4. The method of claim 1, wherein the radioactive seeds are loose.

5. The method of claim 1, wherein the radioactive seeds are in a closed container.

6. (Canceled)

7. The method of claim 5, wherein the closed container carries, during sterilisation, a label or marker indicating the contents of the closed container.

8. The method of claim 1, wherein a plurality of containers of radioactive seeds, comprising the same or different numbers of radioactive seeds, are sterilised together.

9. The method of claim 1, wherein the radioactive seeds comprise ^{125}I-radioiodine or ^{103}Pd-palladium.

10. The method of claim 1, wherein the radioactive seeds are free of moisture.

11. (Canceled)

12. A product comprising one or more sterilized radioactive seeds wherein the seeds are sterilised by the dry heat sterilisation process of claim 1.

13. The product of claim 12, where the radioactive seeds are in a closed container.

14. (Canceled)

15. The product of claim **13**, wherein the closed container carries a marker or label giving details of the contents.

16. (Canceled)

17. (Canceled)

18. The product of claim 12, wherein the dose distribution of each radioactive seed is substantially isotropic.

19. The product of claim 12, wherein the radioactive seeds comprise ^{125}I-radioiodine or ^{103}Pd-palladium.

20. (Canceled)

IX. EVIDENCE APPENDIX

Appellants hereby list the following patents that the Examiner cites against the present invention:

U.S. Patent No. 5,460,592 ("Langton");

U.S. Patent No. 5,863,790 ("Bolea"); and

U.S. Patent No. 6,106,455 ("Kan").

This is the evidence relied upon by the Examiner for rejection of appealed Claims 1, 3-5, 7-10, 12-13, 15 and 18-19 in the Office Action dated March 28, 2007.

X. RELATED PROCEEDINGS APPENDIX

There are no other appeals or interferences related to the instant appeal.